

**EPA Registration # 239-2727**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

November 5, 2016

Jane Rothwell  
Senior Analyst  
Regulatory Affairs  
The Scott's Company  
P.O. Box 190  
Marysville, OH 43040

Subject: Condition of Registration – Storage Stability and Corrosion Characteristics Data  
Product Name: Ortho Fire Ant Killer 2681  
EPA Registration Number: 239-2727  
Application Date: 15-Jul-2016  
Decision Number: 519885

Dear Ms. Rothwell:

The Agency has reviewed the study submitted to fulfill the conditional data requirement referred to above, in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act. A copy of the review is enclosed. The study (MRID # 49976001) has been classified as acceptable. The condition of registration is considered fulfilled.

If you have any questions, please contact Matthew Aubuchon by phone at 703 347-0477, or via email at [aubuchon.matthew@epa.gov](mailto:aubuchon.matthew@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Kable Bo Davis", enclosed within a large, hand-drawn oval.

Kable Bo Davis, Product Manager 3  
Invertebrate and Vertebrate Branch 1  
Registration Division (7505P)  
Office of Pesticide Programs

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**This Document Contains Confidential Information**

**DATE OUT:** October 25, 2016

**SUBJECT:** STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS  
(830.6320) REVIEW  
ACCELERATED STUDY ☒; ONE YEAR STUDY ☐;  
OVER 1 YEAR STUDY ☐  
MP ☐ EP ☒ EUP ☐  
DP BARCODE No.: 434988 REG. No.: 239-2727  
DECISION No.: 519885 MRID No(s): 499760-01  
PRODUCT NAME: ORTHO FIRE ANT KILLER 2681  
COMPANY: THE SCOTTS COMPANY

**FROM:** Linda Mascall / Bruce Kitchens  
Product Chemistry Team  
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)/RD (7505P)

*Linda Mascall*

*Bruce Kitchens*  
10/25/16

**TO:** Letu Kassa / Kable Davis, RM 03  
Invertebrate and Vertebrate Branch 1 / RD (7505P)

**I. CONCLUSIONS:**

STORAGE STABILITY (830.6317):  
☒ ACCEPTABLE  
☐ UNACCEPTABLE\*  
☐ UPGRADEABLE\*

40CFR158.310 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):  
☒ ACCEPTABLE  
☐ UNACCEPTABLE\*  
☐ UPGRADEABLE\*

40CFR158.310 DATA REQUIREMENT: ☒ SATISFIED ☐ NOT SATISFIED

\* If unacceptable or upgradeable describe the deficiency and provide recommendations

## Comments & Recommendations:

The test substance was stored at 54°C and tested at 2 weeks (approximate) for percent (w/w) active ingredients. The test substance was in contact with the appropriate packaging structure (48 ga clear PET/ink/adhesive/5/0 mil white opaque LIDPE with 4 mil LLDPE throughout the storage period. The LLDPE bag simulated the commercial packaging of the product. The analyst conducted observations to look for physical changes in the product (test substance) such as: cracking, fogging, discoloration, or bleed through.

The active ingredient content remained stable after 2 weeks' storage at 54°C. No corrosive effects were observed during the course of the study.

## II. STUDY SUMMARY

### A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

☒ Yes

☐ No

### B. PRODUCT INFORMATION

Active ingredient(s): Bifenthrin

Label claim(s) Nominal concentration(s) (%): 0.20

Initial concentration(s) of the AI(s) (%) used in the study: 0.207

Lower certified limits (%) based on AI % on the label: 0.18

Lower certified limits (%) based on AI % in the study: 0.1863

### C. EXPERIMENTAL PARAMETERS

Temperature: ☐ Freezer; Room ☐; Warehouse ☐; 54°C ☒; Other ☐

Humidity: Indicate % (if provided)

Duration of study: ☐ 1 year; ☐ over 1 year

Type of container: ☐ Glass; ☐ Metal; ☐ HDPE; ☐ Fluorinated HDPE; ☐ Other

Analysis at intervals: ☒ 0 (initial);

☐ 3 months; ☐ 6 months

☐ 9 months; ☐ 12 months

☐ Over 12 months

#### D. ANALYTICAL METHOD

Method	DETECTOR
Gas chromatography (GC)	<input checked="" type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
Capillary Gas chromatography (CGC)	<input type="checkbox"/> FID (Flame Ionization Detector) <input type="checkbox"/> ECD (Electron Capture Detector) <input type="checkbox"/> N/P (Nitrogen/Phosphorous Detector) <input type="checkbox"/> Other
High Pressure Liquid chromatography (HPLC)	<input type="checkbox"/> UV/VIS - 275 (nm) <input type="checkbox"/> RI (Refractive Index) <input type="checkbox"/> Other
GC-MS / LC-MS	Specify
Other	Specify

#### E. RESULTS

Initial	0.207
2 weeks	0.211

**The Scotts Company LLC***and Subsidiaries*

July 15, 2016

Document Processing Desk  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

ATTN: Kable Davis (PM 3)  
Invertebrate-Vertebrate Branch 1

SUBJECT: Ortho Fire Ant Killer 2681  
EPA Reg. No. 239-2727  
Product Chemistry Submission (OPPTS Guidelines- Storage Stability and  
Corrosion- 830.6317 and 830.6320)

Dear Mr. Davis:

The Scotts Company d/b/a The Ortho Group is submitting storage stability and corrosion study (OPPTS Study Guidelines 830.6317 and 830.6320) to support EPA Registration No. 239-2727, Ortho Fire Ant Killer 2681.

The requirement outlined in the Notice of Pesticide Registration dated 8-7-15, comment # 3, requested storage stability and corrosion only. We are providing a complete product chemistry study based on the Alternate formula B (dated 06/05/2014) that we intend on producing to satisfy these requirements.

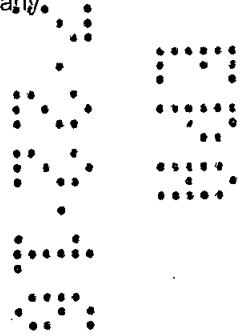
Please find the following documentation in support of this submission:

- Application for Pesticide Registration Form (8570-1)
- Transmittal Document
- Three (3) copies of Physical and Chemical Characteristics study

Please contact me at 937-578-5984 or by email at [Jane.Rothwell@Scotts.com](mailto:Jane.Rothwell@Scotts.com) should you have any questions regarding this submission.

Regards,

Jane Rothwell  
Sr. Analyst, Regulatory Affairs  
Enclosures



TRANSMITTAL DOCUMENT

1. NAME AND ADDRESS OF SUBMITTER:

The Scotts Company d/b/a The Ortho Group  
PO Box 190  
Marysville, Ohio 43040

2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

Submission of Product Chemistry in response to Notice of Pesticide Registration dated: 8-7-15  
Ortho Fire Ant Killer 2681  
EPA Reg. No. 239-2727

3. TRANSMITTAL DATE:

July 15, 2016

4. LIST OF SUBMITTED STUDIES:

Volume	Study Title	Guideline Number	MRID
I	<u>Administrative Materials</u>  Cover Letter  Transmittal Document  EPA Form 8570-1, Application for Pesticide Registration	N/A	
II	Fire Ant Killer: EPA Reg. No. 239-2727: Physical and Chemical Characteristics : Color, Physical State, Odor, Oxidation/Reduction Potential, pH, Granular Bulk Density, Corrosion, and Storage Stability, Author: John Grossenbacher, July 14, 2016, SS-351, Total pages 15	830.6302 830.6303 830.6304 830.6314 830.7000 830.7300 830.6320 830.6317	<b>49976001</b>

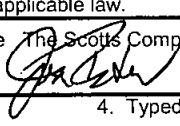
Company Official: Jane Rothwell, Sr. Analyst, Regulatory Affairs

Signature: \_\_\_\_\_

Company Name: The Scotts Company d/b/a The Ortho Group

Company Contact: Jane Rothwell

Phone Number: 937-578-5984

<b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 239-2727		2. EPA Product Manager Kable Bo Davis	
4. Company/Product (Name) The Ortho Group / Ortho Fire Ant Killer 2681		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code)  The Scotts Company d/b/a The Ortho Group PO Box 190 Marysville, OH 43040  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:  EPA Reg. No. _____  Product Name _____	
<b>Section II</b>			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated: <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Submission of storage stability and corrosion in response to EPA conditional letter dated 8-7-15 to satisfy OPPTS Guidelines 830.6317 and 830.6320. See cover letter for details. Email: Jane.Rothwell@Scotts.com			
<b>Section III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No  <b>*Certification must be submitted</b>	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt.    No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt.    No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) bag/ bottle
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
<b>Section IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jane Rothwell		Title Sr. Analyst, Regulatory Affairs	
		Telephone No. (Include Area Code) (937) 578-5984	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamp)
2. Signature BY: 		3. Title Sr. Analyst, Regulatory Affairs	
4. Typed Name Jane Rothwell		5. Date July 15, 2016	



# PROCESSING REQUEST

Reg # 239-2727

Decision # 499128

Description: new product

Electronic Label & Letter  
(see PPLS):

OR

Non Electronic  
Label & Letter  
(Scanning required):

☒ Dated: 8 / 7 / 15

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 6/5/14

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Maggie Rudick

Division: RD/IVB1

Phone: 703-347-0257

Date: 8 / 7 / 2015



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

239-2727

Date of Issuance:

8/7/15

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

ORTHO FIRE ANT KILLER 2681

Name and Address of Registrant (include ZIP Code):

Jane Rothwell  
The Scotts Company d/b/a The Ortho Group  
P.O. Box 190  
Marysville, OH 43040

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Kable Bo Davis, Product Manager 3  
Invertebrate & Vertebrate Branch I  
Registration Division (7505P)

Date:

8/7/15

2. You are required to comply with the data requirements described in the DCIs identified below:

- a. Bifenthrin      GDCI-128825-902  
                         GDCI -128825-1114  
                         GDCI -128825-1158  
                         GDCI -128825-1159

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCIs listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: [http://www.epa.gov/oppsrrd1/contacts\\_prd.htm](http://www.epa.gov/oppsrrd1/contacts_prd.htm)

- 3. The data requirements for storage stability (Guideline 830.6317) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.
- 4. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, "EPA Reg. No. 239-2727."
- 5. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 06/05/2014
- Alternate CSF A dated 06/05/2014
- Alternate CSF B dated 06/05/2014

If you have any questions, please contact Maggie Rudick by phone at 703-347-0257, or via email at [rudick.maggie@epa.gov](mailto:rudick.maggie@epa.gov).

Enclosure

NOTE:

**Bold, italicized text is information for the reader and is not part of the label.**  
[Bracketed information is optional text]. Text separated by ♦ denotes and/or options.

EPA Reg. No. 239-New

## Ortho Fire Ant Killer 2681

Alternate Brand Names

Ortho Fire Ant Killer Broadcast Granules

Ortho Fire Ant Broadcast Granules

Ortho Fire Ant Granules

Ortho Fire Ant Killer Granules

For residential lawn use only

Active Ingredient:

Bifenthrin\*..... 0.20%

Other Ingredients..... 99.80%

Total..... 100.00%

\*Cis isomers 97% minimum, trans isomers 3% maximum.

**KEEP OUT OF REACH OF CHILDREN**

**CAUTION**

See back /panel/ [of] bag for additional precautionary statements.

**NET WT.** XXX LBS / XXX KG

**PRECAUTIONARY STATEMENTS** [icon]

**HAZARDS TO HUMANS & DOMESTIC ANIMALS**

**CAUTION:** Harmful if swallowed, absorbed through skin, or inhaled. Causes moderate eye irritation.

Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wear long sleeved shirt and long pants, shoes, socks and chemical resistant gloves.

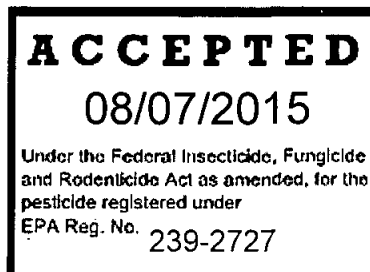
**User Safety Recommendations:** User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet. User should remove clothing/personal protective equipment (PPE) immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

**ENVIRONMENTAL HAZARDS:** This product is extremely toxic to fish and aquatic invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutter or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area. Sweeping any product that lands on a driveway sidewalk, or street, back onto the treated area of the lawn will help to prevent run off to water bodies or drainage systems.

**FIRST AID:**

- If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person
- If on skin or clothing: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
- If inhaled: Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for treatment advice.
- If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Note to Physician: This product is a pyrethroid. If large amounts have been ingested, milk, cream and other digestible fats and oils may increase absorption and so should be avoided. Emergency Assistance: Call **1-800-225-2883**. [phone icon]



## NOTE:

EPA Reg. No. 239-New

**Bold, italicized text is information for the reader and is not part of the label.**

[Bracketed information is optional text]. Text separated by ♦ denotes and/or options.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Apply this product directly to the lawn. Water treated area as directed on this label. Do not water to the point of run-off.

Do not make applications in the rain. Do not apply to hard surfaces such as sidewalks, driveways, and streets where the product is likely to wash off into sewers and waterways.

In New York State, this product may not be applied to any grass or turf area within 100 feet of a water body (lake, pond, river, stream, wetland, or drainage ditch). In New York State, do make a single repeat application of this product if there are signs of renewed insect activity, but not sooner than two weeks after the first application.

Do not allow people and pets to re-enter treated areas until granules have been watered in and area has dried.

**Application Instructions**

Broadcast Treatment	Apply uniformly over your lawn using the suggested spreader settings. Water lawn after application to wash granules from the lawn foliage. If the soil is not moist, then it is important to irrigate before application.
Mound Treatment	Apply ½ cup of Ortho Fire Ant Killer 2681 [product name] over each fire ant mound. A 3 ft. diameter circle around the mound should also be treated. If the soil is not moist, then it is important to irrigate before application. After applying the product, drench the mounds with 2 gallons of water.
Helpful Hints	<ul style="list-style-type: none"> <li>• For best results, apply during morning or late evening when it is cool and the ants are most active.</li> <li>• Don't treat just the infested areas of the lawn where mounds are visible. Treat the entire lawn area to control reinfestation of fire ants from neighboring areas.</li> <li>• Control will be optimized by combining broadcast applications that will control foraging workers and newly mated fly-in queens with mound treatments that will kill existing colonies.</li> <li>• For best results, apply when temperatures are between 65° and 80°F.</li> <li>• [Optional] For extended fire ant control, apply Ortho® Fire Ant Killer 2681 [product name] in spring and late summer.</li> </ul>
Important	<ul style="list-style-type: none"> <li>• Food utensils, such as teaspoons and measuring cups, must not be used for food purposes after use with pesticides.</li> </ul>

**[Spreading/Spreader Tips**

For best results]

Spreader settings are approximate. You may need to adjust for proper coverage.

Spreader	Spreader Settings - Covers 5,000 sq. ft.	Directions
Drop Spreaders	X	Mow lawn first if grass is tall enough to touch the bottom of the spreader. First apply two header strips. Operate spreader

## NOTE:

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EPA Reg. No. 239-New

		the longest way of the lawn. Overlap wheel marks to ensure uniform coverage. Shut off spreader when you have reached the header strips or stopped.
EasyGreen® Rotary	X	Slide shut-off lever to the right; application automatically starts and stops when you do. For complete coverage make each pass about 30 inches from the previous one so some overlapping occurs.
SpeedyGreen® Rotary / Scotts Basic™ / Standard™ / Deluxe™ / Edgeguard® / Lawn Pro®	X	[Align hopper arrow with previous wheel track to ensure even coverage.] Shut off spreader anytime you stop. For complete coverage make each pass about five feet from the wheel track, so some overlapping occurs. Do not apply this product to vegetables.

## Additional Spreader Settings

EZ Drop, Republic (#530) -----(X)  
EZ Broadcast, Republic (#540) -----(X)  
Scotts® Handy Green® II-----(X)  
Scotts® Easy™ Hand Held Spreader----- (X)  
ORTHO® Whirlybird® Multipurpose Spreader----- (X)

[Illustrations: spreading patterns]

[Ortho Fire Ant Killer 2681/[product name] kills the following types of ants:

Fire Ants  
Odorous  
Pyramid  
Pavement]

[Kills

[Scorpions]\* \* broadcast application only

## STORAGE AND DISPOSAL [icon][trash can]



**PESTICIDE STORAGE:** Keep out of reach of children and animals. Store in original bag/container only. Store in a clean, dry, well ventilated place and avoid excess heat. For bags/containers after partial use, reseal opened bag/container by folding top down and securing.

**PESTICIDE DISPOSAL AND CONTAINER HANDLING:** Nonrefillable container. Do not reuse or refill this container. If empty: Place in trash or offer for recycling, if available. If partly filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

**NOTICE:** To the extent consistent with applicable law, buyer assumes all risks of use, storage or handling of this product not in accordance with directions.

## NOTE:

EPA Reg. No. 239-New

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**The ORTHO Guarantee:** If for any reason you, the consumer, are not satisfied with this product, mail us your original proof of purchase to obtain a full refund of your purchase price.  
Questions and/or Comments Call 1-800-225-2883 [phone icon]

Manufactured for / Sold By  
The ORTHO Group  
P.O. Box 190  
Marysville, OH 43040

EPA Reg. No. 239-NEW  
EPA Est. 9198-OH-1<sup>M</sup>, 9198-OH-2<sup>O</sup>, 9198-AL-001<sup>L</sup>  
Superscript is first letter of lot number  
Made in USA

*Optional Text and Claims**The following claims: May or may not appear on any label panel or in advertising.**May be preceded by "new" or "now" for six months following commercial introduction.***FIRE ANT Illustration**

<b>PRODUCT FACTS</b>	
KILLS [listed ants][listed insects]	Fire Ants [and other listed insects]
<b>WHERE TO USE</b>	On residential lawns
<b>AMOUNT TO USE /HOW TO USE</b>	Broadcast Treatment: Apply uniformly over your lawn using the suggested spreader settings. Mound Treatment: Apply ½ cup per mound. Drench mound with 2 gallons of water.
<b>COVERAGE</b>	Treats up to 5,000 square feet. <b><i>Note to PM: Coverage will vary depending on package size, see chart in marketing claims. This claim is for a 11.5 lb bag</i></b>

***Optional Marketing Claims (claims may appear on any or all label panels): Note to PM: Any combination of approved claims may be inserted dependent upon sites listed on the market label and product size***

1. Kills Mounds and The Queen
2. [Provides] 6 month Fire Ant Control/Protection
3. Keeps New Mounds from forming
4. Protects the entire lawn from fire ants for up to 6 months
5. Controls Fire Ant Mound formation
6. Kills foraging Fire Ants
7. Controls new Fire Ant mounds from forming for up to 6 months
8. Ready-To-Use
9. Kills fly-in Queens
10. Kills Fire Ants [and other Listed Insects]
11. Quick/Immediate release granules and deep penetrating formula
12. Controls [and][kills] fire ants for [1,2,3,4,5] 6 months
13. [1,2,3,4,5] 6 month fire ant control
14. Apply in spring and fall for year round [long] control
15. Protects your/the lawn from fire ants for [1,2,3,4,5] 6 months
16. [Re-entry icon] Do not allow people and pets to re-enter treated areas until granules have been watered in and area has dried.
17. Controls/Kills/Suppresses [fire ant] mounds in 15 minutes (Guaranteed Kill or your money back)
18. 15 minute [fire ant] mound control
19. Kills fire ant mounds in 15 minutes
20. Creates/Provides a 6 month fire ant barrier

## NOTE:

EPA Reg. No. 239-New

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21. Starts killing/to kill fire ant mounds in [15 ] minutes

## Value claims

1. X% more than X size!
2. Bonus Size
3. Combo Pack
4. Wow (Pack)
5. Value size
6. Value pack
7. Great value
8. Exclusive to Club Stores!
9. Exclusive Club (Bonus) Size!
10. Value/Bonus Size – 2-pack!
11. Guarantee kill or your money back
12. 2 Step Value Pack
13. 2 Steps to controlling fire ants
14. Fire Ant 2/Two Step: Mound plus/+/&/and Broadcast
15. Use a two-step method/process against fire ants: Mound and/& (plus/+) broadcast
16. Fire Ant 2-Step [Method]
17. Step 1 [:Mound Treatment]
18. Step 2 [:Broadcast Treatment]
19. Step 1: Kill the Mound
20. Step 2: Protect the Ground
21. Fire Ant 2-Step [Method]: Step 1 (mound treatment) + Step 2 (broadcast)
22. Use [this product] with a registered product for mound treatment [As part of the Fire Ant 2 Step]

## Coverage claims

1. Covers/treats up to XXX sq. ft. *Note to PM-see table below*

Amount of Product (rate of active ingredient is 0.2 lb per acre)	Treats xx sq feet
Xx lb bag.	Xx lb / .0023 lb sq ft = Covers xx sq ft
.0023 lb	1 sq ft
2.3 lb	1000 sq ft
11.5 lb	5000 sq ft
23 lb	10,000 sq ft

## Packaging claims:

1. front
2. scissors/ zipper
3. DO NOT CUT BELOW DOTTED LINE / CUT HERE TO OPEN
4. DO NOT CUT BELOW DOTTED LINE

**Optional Marketing Claims (claims may appear on any or all label panels):** *Note to PM: Any combination of approved claims may be inserted dependent upon sites listed on the market label and product size.*

[Brand]	Ortho
[Sub-Brand]	Fire Ant Killer 2681 /alternate brand name
[Marketing Call-out]	Kills Mounds and The Queen



## NOTE:

**Bold, italicized text is information for the reader and is not part of the label.**

[Bracketed information is optional text]. Text separated by ♦ denotes and/or options.

EPA Reg. No. 239-New

	<ol style="list-style-type: none"> <li>1. Apply in spring and fall for year round [long] control</li> <li>2. Treats up to 5,000 square feet. <i>Note to pm-will change depending on bag size</i></li> <li>3. Kills fly-in Queens</li> <li>4. Quick/Immediate release granules and deep penetrating formula</li> <li>5. Kills foraging Fire Ants</li> </ol>
[Product Facts:]	<p>Product Facts:</p> <p>What it Does: Kills Fire Ants and Controls new mounds from forming for up to 6 months</p> <p>Where to Use: On residential lawns</p> <p>When to use: Apply during morning or late evening when it is cool and the ants are most active</p> <p>[Re-entry icon] Do not allow people and pets to re-enter treated areas until granules have been watered in and area has dried.</p> <p>Questions &amp; Comments: (phone &amp; computer icon) Call 1-800-225-2883 or visit our website at <a href="http://www.ortho.com">www.ortho.com</a></p>
[Ortho Guarantee]	<p>[†]The ORTHO® Guarantee.</p> <p>[†] If for any reason you, the consumer, are not satisfied with this product, mail us your original proof of purchase to obtain a full refund of your purchase price.</p>
[UPC]	UPC Placeholder
[Standard Copy]	<p>© 2015 The ORTHO Group. World rights reserved.</p> <p>Sold by The ORTHO Group PO Box 190, Marysville, OH 43040</p>
[EPA Info]	<p>EPA Reg. No. 239-NEW</p> <p>EPA Est. XXX, XXX, XXX, XXX, XXX, XXX</p> <p>Superscript is first letter of lot number.</p>

NOTE:

***Bold, italicized text is information for the reader and is not part of the label.***

[Bracketed information is optional text]. Text separated by ♦ denotes and/or options.

EPA Reg. No. 239-New

[Component Number]	Component # Placeholder
[Other]	(Recycle Symbol)

## Rudick, Maggie

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**From:** Bohnenblust, Eric  
**Sent:** Tuesday, August 04, 2015 7:32 AM  
**To:** Rudick, Maggie  
**Subject:** RE: Label Request - EPA File Symbol 239-ETET

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Maggie,

As we discussed previously they can't mention another product like they do in claims 21 and 22. Also is this product the OFAK pack shot? That's not a name on the label so I'm not sure.

Claim 22 should specify that it is part 2, not just part of the 2-step.

Let me know if that doesn't make sense or jive with what you are thinking.

Thanks.

Eric

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**From:** Rudick, Maggie  
**Sent:** Monday, August 03, 2015 5:04 PM  
**To:** Bohnenblust, Eric  
**Subject:** FW: Label Request - EPA File Symbol 239-ETET

Eric –

I spoke with you briefly about this label and the efficacy claims. Scott's outlined the claims that they wanted to review in the attached PDF cover letter. Would you mind taking a look and letting me know what you think?

Thanks!

Maggie

**From:** Rothwell, Jane [<mailto:jane.rothwell@scotts.com>]  
**Sent:** Monday, August 03, 2015 2:12 PM  
**To:** Rudick, Maggie  
**Subject:** Re: Label Request - EPA File Symbol 239-ETET

Hi Maggie

Attached is the revised label and cover letter with regard to the efficacy review and changes you requested for this label, 239-ETET.

We made most of the changes, and also made some revisions based on the efficacy review. I highlighted sections that were updated and used red to indicate revisions or new.

Please review and let me know if any additional changes/edits are required. Once finalized, I will provide you with a "clean" label.



***The Scotts Company LLC***

*and Subsidiaries*

Sent via email: August 3, 2015

**ATTENTION:** Maggie Rudick  
Invertebrate-Vertebrate Branch 1

**SUBJECT:** The Scotts Company d/b/a The Ortho Group  
Ortho Fire Ant Killer 2681  
EPA File Symbol 239-ETET

Dear Maggie:

The Scotts Company d/b/a The Ortho Group (hereafter Scotts) is responding to the efficacy review and requested label changes submitted via email on July 24, 2015.

Scotts has made most of the changes requested and/or revised claims in accordance with the efficacy evaluation.

Please note the following:

- First Aid statements were revised and User Safety heading was added.
- Removed the red harvester ants and added Scorpions (as optional) (See Mrid 46508101)
  - Kept Argentine ants (since they are not public health pests)(please advise why this was struck)
  - Kept "listed insects" (since there are additional insects on the label)
- Added additional bifenthrin mitigation language to Directions for Use (DFU): "Do not apply to hard surfaces such as sidewalks, driveways, and streets where the product is likely to wash off into sewers and waterway"
- Revised the DFU to 3 ft radius and 2 gallons of water
- Revised the following claims (in accordance with the efficacy review):
  - Protects the entire lawn from fire ants for up to 6 months
  - Protects your/the lawn from fire ants for [1,2,3,4,5] 6 months
  - Struck "~~Fast Acting, Long Lasting~~ [fire ant control]" and Revised to: "Kills fire ant mounds fast/in [15] minutes"
  - Struck "~~Starts killing fast/immediately~~" and Revised to: Starts killing/to kill fire ant mounds fast/immediately/in [15]minutes
  - Added a table as a "note to PM" to clarify coverage claims based on package size
  - Revised the following claim- [Provides] 6 month Fire Ant Control/Protection
  - Added/revised: "Use a two-step method/process against fire ants: Mound and/& (plus/+) broadcast" (approved in efficacy review)
  - Revised the two step claims and added a note to PM to clarify use\*

\*Note- The intention of the two step claims would be to have the option of using this product and/or this product in conjunction with another Scotts EPA approved product for fire ants using both a broadcast treatment and a mound treatment to control fire ants.

Please contact me at 937-578-5984 or by email at [Jane.Rothwell@Scotts.com](mailto:Jane.Rothwell@Scotts.com) should you have any questions regarding this submission.

Sincerely,

Jane Rothwell  
Sr. Analyst, Regulatory Affairs

## Rudick, Maggie

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**From:** Rothwell, Jane <jane.rothwell@scotts.com>  
**Sent:** Wednesday, August 05, 2015 1:53 PM  
**To:** Rudick, Maggie  
**Subject:** Re: Label Request - EPA File Symbol 239-ETET  
**Attachments:** 239-ETET updated with EPA comments 8-5-15 JRdoc.doc

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Hi Maggie

I attached the revised label with the changes.

Thanks for your help on this.

Regards,

Jane

On Wed, Aug 5, 2015 at 12:45 PM, Rudick, Maggie <[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)> wrote:

Jane –

I addressed your questions below in red.

Maggie Rudick  
U. S. Environmental Protection Agency  
Office of Pesticides Program  
Registration Division; Invertebrate & Vertebrate Branch I  
(703) 347-0257  
[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)

**From:** Rothwell, Jane [mailto:[jane.rothwell@scotts.com](mailto:jane.rothwell@scotts.com)]  
**Sent:** Tuesday, August 04, 2015 1:45 PM  
**To:** Rudick, Maggie  
**Subject:** Re: Label Request - EPA File Symbol 239-ETET

Maggie

Thank you the quick response on the changes.

Two questions/issues:

1. The efficacy review says - see (B) (4) (mrid 49546203) Conclusion: The study is acceptable to support claims of "starts killing in minutes" and "15 minute killing claims" against fire ants for applications of 1/2 cup of a 0.2% granular bifenthrin product....of water." Is there a reason why we have to specify "15" and not be able to say : Starts to kill/killing fire mounds in minutes? (claim 21). Additionally, the label approved for FMC, reference EPA 279-3344- this label has claims of starts killing in minutes/fast acting/kills fire ants fast. Although this has a combination of actives (bifenthrin and zeta-cypermethrin) FMC relied on the same study we submitted. We realize requirements for "fast" may be under new scrutiny, but we are trying to be competitive with our claims (see "Over n Out" market label attached). A claim of "Starts killing in minutes" seems reasonable under these circumstances and is supported by the efficacy review.

Jane – You can keep the “starts killing in minutes” claims, but must remove the fast/immediately statements.

2. As for the reference to other products (deletion of claims 21 and 22 and "note to PM- "you cannot reference other products") -The attached label was stamped approved May 2014- EPA Reg No. 9688-277- Chemsico Insecticide -see page 2 - Cross marketing claims. Can you explain the difference between these label claims and what we are trying to accomplish on ours?

Jane – While I understand your concern that cross marketing claims have sometimes been approved on other labels, we are not in a position to allow new cross marketing claims. We will be addressing labels which already have this language. You can have language such as “Use this product with a registered product for broadcast application”, but cannot specifically mention a name or reg #.

Other than these two questions noted, I have made all the revisions.

I will wait to hear back before submitting final.

Thanks for your help,

Jane

On Tue, Aug 4, 2015 at 11:55 AM, Rudick, Maggie <[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)> wrote:

Jane –

For the scorpion claim, make sure to qualify that is it for broadcast application only.

Maggie Rudick  
U. S. Environmental Protection Agency  
Office of Pesticides Program  
Registration Division; Invertebrate & Vertebrate Branch I  
(703) 347-0257  
[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)

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**From:** Rudick, Maggie  
**Sent:** Tuesday, August 04, 2015 11:31 AM  
**To:** 'Rothwell, Jane'  
**Subject:** RE: Label Request - EPA File Symbol 239-ETET

Jane –

We looked over your label and are requesting some additional revisions. I noted these revisions in the attached document as sticky notes.

1. Page 2 – change “For Best Results” to “Application Instructions”
2. Page 3 - Argentine ants are public health pests. Since data the submitted does not support argentine ants, this must be deleted.
3. Page 4 – Kills [ants] must be revised to Kills [listed ants]
4. Page 4-5 – Claims 17,18,19, and 21 – remove brackets around [15] minutes
5. Page 5 – Remove ‘fast’ and ‘immediate’ from kill claims
6. Page 5 – Under value claims, remove claims 21 and 22 and note to PM

Please let me know if you have any questions.

Maggie Rudick  
U. S. Environmental Protection Agency  
Office of Pesticides Program  
Registration Division; Invertebrate & Vertebrate Branch I  
(703) 347-0257  
Rudick.Maggie@epa.gov

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**From:** Rudick, Maggie  
**Sent:** Tuesday, August 04, 2015 8:48 AM  
**To:** 'Rothwell, Jane'  
**Subject:** RE: Label Request - EPA File Symbol 239-ETET

Jane –

Thanks for sending this. We will get back to you later this week with a response.

Maggie Rudick  
U. S. Environmental Protection Agency  
Office of Pesticides Program  
Registration Division; Invertebrate & Vertebrate Branch I  
(703) 347-0257  
Rudick.Maggie@epa.gov

**From:** Rothwell, Jane [<mailto:jane.rothwell@scotts.com>]  
**Sent:** Tuesday, August 04, 2015 8:35 AM



**To:** Rudick, Maggie

**Subject:** Re: Label Request - EPA File Symbol 239-ETET

Hi Maggie

Please confirm that you received this.

Thank you,

Jane Rothwell

On Mon, Aug 3, 2015 at 2:12 PM, Rothwell, Jane <[jane.rothwell@scotts.com](mailto:jane.rothwell@scotts.com)> wrote:

Hi Maggie

Attached is the revised label and cover letter with regard to the efficacy review and changes you requested for this label, 239-ETET.

We made most of the changes, and also made some revisions based on the efficacy review. I highlighted sections that were updated and used red to indicate revisions or new.

Please review and let me know if any additional changes/edits are required. Once finalized, I will provide you with a "clean" label.

Thank you,

Jane Rothwell

On Tue, Jul 28, 2015 at 5:14 PM, Rudick, Maggie <[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)> wrote:

Jane –

The Predecisional date is August 21, so I'd like to resolve any labeling issues by the end of next week.

Maggie Rudick  
U. S. Environmental Protection Agency  
Office of Pesticides Program  
Registration Division; Invertebrate & Vertebrate Branch I  
[\(703\) 347-0257](tel:(703)347-0257)  
[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)

**From:** Rothwell, Jane [<mailto:jane.rothwell@scotts.com>]  
**Sent:** Tuesday, July 28, 2015 2:55 PM  
**To:** Rudick, Maggie  
**Subject:** Re: Label Request - EPA File Symbol 239-ETET

Hello Maggie

Thanks for the note. I will review with my team and get back with you next week. I am off 1/2 day Thursday and Friday so short week for me. Will touch base early next week. I have the PRIA date as Sept 4, 2015 for this, correct?

Thank you,

Jane Rothwell

On Fri, Jul 24, 2015 at 3:33 PM, Rudick, Maggie <[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)> wrote:

Jane –

We've reviewed your proposed label for 239-ETET and are requesting label revisions. I've attached the efficacy review as well as a highlighted version of your proposed label addressing the following concerns:

1. Revise Precautionary Language and First Aid Statements
2. Remove 'garden' uses
3. Clarify mound treatment applications
4. Remove argentine and red harvester ants
5. Clarify "insects" in marketing statements
6. Remove marketing statements identified in the efficacy review

Should you have any questions about these revisions, please let me know. Thank you and have a nice weekend.

Maggie Rudick  
U. S. Environmental Protection Agency  
Office of Pesticides Program  
Registration Division; Invertebrate & Vertebrate Branch I  
(703) 347-0257  
[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)

**From:** Rothwell, Jane [<mailto:jane.rothwell@scotts.com>]  
**Sent:** Monday, June 22, 2015 2:26 PM  
**To:** Rudick, Maggie  
**Subject:** Re: Label Request - EPA File Symbol 239-ETET

The application rate is 0.2 lb of bifenthrin per acre. 2.3 lb pf product per 1000 sq ft, 11.5 lb product per 5000 sq ft... etc. Did you need for us to update the label now or wait until your review of the label later?

On Mon, Jun 22, 2015 at 9:13 AM, Rudick, Maggie <[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)> wrote:

Jane –

Our efficacy reviewer is looking over your label/data now, so no changes/additions at this time – at this point, clarification on the intended application rate is the only thing we need. Once we get the efficacy review back, I will send you all necessary labeling revisions through our primary review, if necessary.

Maggie Rudick  
U. S. Environmental Protection Agency  
Office of Pesticides Program  
Registration Division; Invertebrate & Vertebrate Branch I  
(703) 347-0257  
[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)

**From:** Rothwell, Jane [<mailto:jane.rothwell@scotts.com>]  
**Sent:** Monday, June 22, 2015 9:11 AM  
**To:** Rudick, Maggie  
**Subject:** Re: Label Request - EPA File Symbol 239-ETET

Maggie

I am back in the office. Trying to catch up! I will review this label with our R&D team and get back with you hopefully mid week. I also have a few other changes/additions I would like to make to this label w/regard to additional bifenthrin mitigation language and claims for our two step program.

Is there anything else you need from me at this point?

Regards

Jane Rothwell

On Thu, Jun 18, 2015 at 3:49 PM, Rudick, Maggie <[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)> wrote:

Jane –

We are looking over your label and the application rate is not clearly identified. Please clarify the intended application rate.

Your directions say a bag treats 5,000 sq ft, but we don't know if that is a 1lb bag, 12 lb bag, etc. The maximum rates needs to be clearly identified on the label.

Thank you,

Maggie Rudick  
U. S. Environmental Protection Agency  
Office of Pesticides Program  
Registration Division; Invertebrate & Vertebrate Branch I  
(703) 347-0257  
[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)

**From:** Rothwell, Jane [<mailto:jane.rothwell@scotts.com>]  
**Sent:** Wednesday, February 04, 2015 8:49 AM  
**To:** Rudick, Maggie  
**Subject:** Re: Label Request - EPA File Symbol 239-ETET

Maggie

Attached are the following documents per your request: (adobe files)

- Cover letter
- Proposed labeling
- Data Matrix- private version
- Formulator's exemption statement

Please let me know if you need anything else from me at this time.

Regards,

Jane Rothwell

On Tue, Feb 3, 2015 at 5:30 PM, Rudick, Maggie <[Rudick.Maggie@epa.gov](mailto:Rudick.Maggie@epa.gov)> wrote:

Jane –

We received your 1/6/15 submission for “Ortho File Ant Killer 2681”. To help our review, please email me electronic versions of:

1. Cover letter
2. Proposed labeling
3. Data Matrix (public version not needed) and formulators exemption



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM:**

To: Maggie Rudick

From: Eric Bohnenblust, Ph.D., Entomologist

Secondary Review: Kevin Sweeney, Senior Entomologist

Date: July 7, 2015

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

**THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION**

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 426477

Decision no.: 499128

Submission no: 962823

Action code: R310

Product Name: Ortho Fire Ant Killer 2681

EPA Reg. No or File Symbol: 239-ETET

Formulation Type: spreadable granular formulation

Ingredients statement from the label with PC codes included:

Bifenthrin 0.2% PC: 128825

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m<sup>2</sup> or mg/cm<sup>2</sup> or mg/kg body weight as appropriate):

0.2 lb bifenthrin/acre [2.3 lb product (0.0046 lb bifenthrin)/1000 ft<sup>2</sup>, 11.5 lb product (0.023 lb bifenthrin)/5000 ft<sup>2</sup>, 23 lb product (0.046 lb bifenthrin)/10000 ft<sup>2</sup>]

Use Patterns: Ant mound treatment, outdoor broadcast application

**I. Action Requested:** The registrant is requesting review of 13 MRIDs to support efficacy claims against fire ants, and harvester ants. Specifically, the registrant is requesting re-review of MRID 48387402 with regard to speed to kill claims.

**II. Background:** The registrant cited 12 MRIDs and submitted 1 new MRID to support residual and speed to kill efficacy claims against fire ants. The registrant also is proposing efficacy claims against ant mounds and queens and harvester ants. The 12 cited MRIDs have been reviewed for other products, and short summaries of previous reviews are presented below. In addition, MRID 48387402 was reviewed to determine whether it supports speed to kill claims. Reviewer contacted the registrant regarding the intended label application rate because it was not specified on the label and the registrant responded that the intended application rate is 0.2 lb bifenthrin/acre.

**III. MRID Summary: (primary review is attached)**

**(A). Previously Reviewed MRIDs:**

46180801. Length of Red imported Fire Ant Control using Bifenthrin as Broadcast Treatment at 0.2 lb. AI/A

**and Mound Treatment for Control of RIFA, EPA Reg. No. 239-2681.**

(1) **Conclusion: Acceptable.** The experiments in this study tested a broadcast application of granular bifenthrin at 0.2 lb a.i./acre against imported fire ant and demonstrated 95% control for up to 6 months.

**44021901. Efficacy of Broadcast Applications of Bifenthrin Granular Formulations for Imported Fire Ant Control in Turfgrass and Electrical Transformers.**

(1) **Conclusion: Supplemental.** One experiment tested a field application of granular applied bifenthrin at 0.125 lb a.i./acre against imported fire ant alate queens and demonstrated effective control for up to 4 months. The other tests used 0.25 lb bifenthrin/acre as the lowest application rate, because this rate is higher than the recommended label rate of 0.2 lb bifenthrin/acre these studies do not support efficacy claims for the proposed product.

**44137401. Efficacy of Broadcast Applications of Bifenthrin Liquid and Granular Formulations for Deer Tick (*Ixodes* sp.) Control in Turfgrass.**

(1) **Conclusion: Acceptable.** This study tested a bifenthrin rate of 0.2 lb per acre and found acceptable levels of control against deer ticks; however, residual claims are not acceptable. This study shows acceptable efficacy against deer ticks of a granular bifenthrin treatment at a rate of 0.2 lb bifenthrin/acre; however, data showing efficacy against deer ticks, dog ticks, and lone star ticks are necessary for any tick claims.

**44137402. Efficacy of Broadcast Applications of Bifenthrin Liquid and Granular Formulations for American Dog Tick (*Dermacentor variabilis*) Control in Turfgrass.**

(1) **Conclusion: Acceptable.** This study tested a bifenthrin rate of 0.2 lb per acre and found acceptable levels of control against American dog ticks; however, residual claims are not acceptable. This study shows acceptable efficacy of a granular bifenthrin treatment at 0.2 lb bifenthrin/acre against American dog ticks. However, data showing efficacy against deer ticks, dog ticks, and lone star ticks are necessary for any tick claims.

**44891902. Efficacy of Broadcast Applications of Bifenthrin Liquid and Granular Formulations to Turfgrass for Cat Flea Larval and Adult control.**

(1) **Conclusion: Unacceptable.** This study tested a bifenthrin rate of 0.2 lb per acre and found acceptable levels of control against both cat flea adults for 3 days and larvae for 7 days. However, this study does not support efficacy claims because moribund and dead insects were not separated.

**46809101. Length of Red Imported Fire Ant (*Solenopsis invicta*) Control Using Ortho Fire Ant Killer Granules (EPA Reg. No. 239-2681).**

(1) **Conclusion: Acceptable.** This study tested a bifenthrin rate of 0.2 lb per acre and found greater than 90% control of fire ants through 5 months post application. Control of fire ants dropped to 85% at 6 months post application. This study supports residual efficacy claims against fire ants for up to 5 months.

**46809102. Suppression of Red Imported Fire Ants (*Solenopsis invicta*) Using Ortho Fire Ant Killer Granules (EPA Reg. No. 239-1681).**

(1) **Conclusion: Acceptable.** This study tested a bifenthrin rate of 0.2 lb per acre and found greater than 90% efficacy against fire ants through 28 days post application. This study supports residual efficacy claims against fire ants for up to 28 days.

**46186401. Efficacy of FMC 54800 Granular Formulations for Control of Scorpions and Chiggers.**

(1) **Conclusion: Unacceptable.** This study tested the efficacy of granular bifenthrin against scorpions at a rate of 0.4 lb bifenthrin/acre. The rate tested for scorpions is higher than the labeled rate of 0.2 lb bifenthrin/acre on the



proposed label; therefore, claims against scorpions are not acceptable. The study also tested against chiggers, the efficacy of rates of 0.1 and 0.2 lb bifenthrin/acre with and without fertilizer. Efficacy against chiggers was less than 90% for all treatments at 3 days post exposure, and was only over 90% at 10 days post exposure for the 0.2 lb bifenthrin/acre without fertilizer treatment. Because efficacy was below 90% for all but one measurement point at one rate the data do not support efficacy claims against chiggers.

**46508101. Efficacy of FMC 54800 Granular Pesticide for Control of Scorpions.**

(1) **Conclusion: Acceptable.** Within 4 hours of exposure 95% of scorpions exposed to bifenthrin treated soil died. This study supports kills claims for scorpions at a rate of 0.2 lb bifenthrin/acre.

**48387401. DG-Lite a Rapid Release Granule Technology.**

(1) **Conclusion: Supplemental.** A laboratory study was conducted to demonstrate the physical attributes of Dolomitic limestone pellets compared to peanut hulls when exposed to moisture. The study is supplemental information, showing that the DG-lite granule dissolves faster than peanut hulls.

**48387402. Speed of Fire Ant Control with a Granule Formulation Containing 0.05% zeta-cypermethrin and 0.20% Bifenthrin.**

(1) **Conclusion: Acceptable.** The study is acceptable to support 15 minute killing claims against fire ants for applications of ½ cup product (0.2% granular bifenthrin) directly onto ant mounds and a 3 ft. radius around the mound when mounds are drenched with 2 gallons of water. This study does not support speed of kill claims for broadcast applications.

**45298601. Efficacy of Broadcast Applications of Bifenthrin Granular Formulations for Insect Control in Turfgrass.**

(1) This MRID is a compilation of numerous studies against numerous pests. Two studies are relevant to this proposed product, one testing the efficacy of granular bifenthrin against argentine ants, and another study testing the efficacy of granular bifenthrin against pharoah ants.

(2) **Conclusion: Unacceptable.** Efficacy of a 0.2 lb bifenthrin/acre rate of a 0.2% granular bifenthrin product against argentine ants was less than 75%, and methods for this study were not presented. While the number of pharoah ants captured in petri dishes baited with corn syrup were reduced by 100% for up to 8 days post treatment at a rate of 0.2 lb bifenthrin/acre rate using a 0.2% granular bifenthrin product, this study is not acceptable because replication is not given, there is no confirmed kill, and it is not clear if petri dish traps were placed in the treatments during the same four hour period (e.g., 12:00 – 4:00 PM) on all sample days.

**(B). Newly submitted MRID:**

**49546203. Speed of Fire Ant Control with a Granule Formulation Containing 0.20% Bifenthrin.**

(1) non-GLP

(2) **Methods:** Thirty fire ant mounds were treated with a ½ cup (95 g) of a 0.2% granular bifenthrin product and another 30 mounds were treated with an unknown amount of DG Lite carrier applied directly to the mounds. There were 10 untreated mounds. After application, 2 gallons of water was applied to each mound using enough force to break the mound. Efficacy was assessed using a 1 to 5 rating scale at 1, 2, 3, 4, 5, 10, 15, 20, and 30 minutes and 40 days post application. (Note: This MRID also contains a study from 2010 which was previously submitted as MRID 48387402. The 2010 study is addressed separately under MRID 48387402 above.)

(3) **Results:** Efficacy of the bifenthrin treatment was statistically different from the control and DG Lite carrier treatments at all evaluation times beginning with the 1 minute evaluation. However, 90% mortality was not reached until 15 minutes post application. The bifenthrin treatment killed 100% of treated mounds at 40 days post

application.

(4) **Conclusion:** The study is acceptable to support claims of starts killing in minutes and 15 minute killing claims against fire ants for applications of ½ cup of a 0.2% granular bifenthrin product directly onto ant mounds and a 3 ft. radius around the mound when mounds are drenched with 2 gallons of water. This study does not support speed of kill claims for broadcast applications.

#### **IV. EXECUTIVE DATA SUMMARY:**

(A) The submitted data support kill claims and residual kill claims against fire ants for up to 6 months when applying a broadcast application at a rate of 0.2 lb granular bifenthrin/acre. The data also support claims against fire ants of "Kills in 15 minutes" when applying a mound treatment at a rate of 0.5 cups of product (0.2% granular bifenthrin product) to the mound and a 3 ft radius around the mound and subsequently drenching the mound with 2 gallons of water. In addition, the submitted data support a claim of kills scorpions when applying a broadcast application at a rate of 0.2 lb bifenthrin/acre.

(B) The data do not support speed of kill claims against fire ants for broadcast applications, kill claims against fleas, or any tick claims. The data do show acceptable efficacy against deer ticks and American dog ticks, but data showing efficacy against lone star ticks in addition to deer ticks and dog ticks are necessary for any tick claims.

#### **V. LABEL RECOMMENDATIONS:**

(1) The following changes should be made to the Directions for Use:

In the tables where there are instructions for mound treatments (Pages 2 and 4), the directions should specify to drench the mounds with 2 gallons of water.

Also on page 2 in the mound treatment section of the table, the first sentence should read: Apply ½ cup of Ortho Fire Ant Killer 2681 [product name] over each fire ant mound and a 3 ft. radius around the mound.

The product is packaged in 1 - 12 lb bags and a 23 lb bag. To achieve a rate of 0.2 lb bifenthrin/acre, 1 lb treats 435 ft<sup>2</sup>. In the tables under the Directions for Use the wording should be changed from "treats up to 5000 ft<sup>2</sup>" to the following depending on bag size:

1 lb treats up to 435 ft<sup>2</sup>  
2 lb treats up to 870 ft<sup>2</sup>  
3 lb treats up to 1305 ft<sup>2</sup>  
4 lb treats up to 1740 ft<sup>2</sup>  
5 lb treats up to 2175 ft<sup>2</sup>  
6 lb treats up to 2610 ft<sup>2</sup>  
7 lb treats up to 3045 ft<sup>2</sup>  
8 lb treats up to 3480 ft<sup>2</sup>  
9 lb treats up to 3915 ft<sup>2</sup>  
10 lb treats up to 4350 ft<sup>2</sup>  
11 lb treats up to 4785 ft<sup>2</sup>  
12 lb treats up to 5220 ft<sup>2</sup>  
23 lb treats up to 10000 ft<sup>2</sup>

(2) The following marketing claims are acceptable:

Mound treatment starts killing fire ants in 1 minute  
Mound treatment starts killing fire ants in minutes  
Mound treatment kills fire ants in 15 minutes  
Kills mounds and the queen  
Provides 6 month fire ant control  
Keeps new mounds from forming  
Controls fire ant mound formation  
Kills foraging fire ants

Prevents new fire ant mounds from forming for up to 6 months

Kills fly-in queens

Kills fire ants and other listed\* insects (other listed insects should be listed in a footnote below the claims section)

Apply in spring and fall for year round control

[1,2,3,4,5,6] month [fire] ant<sup>1</sup> control (<sup>1</sup>except pharaoh, carpenter, and harvester ants)

Protects your lawn from [fire] ants<sup>1</sup> for [1,2,3,4,5,6] months (<sup>1</sup>except pharaoh, carpenter, and harvester ants)

Mound treatment kills fire ant mounds in 15 minutes

15 minute fire ant mound control using mound treatment

A 23 lb. bag covers/treats up to 10,000 sq. ft.

Fire ant two step: Mound and (plus/+/&) broadcast

Use as a two-step method (process) against fire ants: Mound and (plus/+/&) broadcast

Protects the entire lawn from fire ants for up to 6 months

Kills the following types of ants:

Fire ants

Odorous

Pyramid

Pavement

(3) The following marketing claims are unacceptable:

Protects the entire lawn for up to 6 months

Fast acting, [long lasting] [fire ant control]

Starts killing fast/immediately

Starts to kill fast/immediately

Use as part of the fire ant 2/two-step method/process (Mound plus/+/&/and Broadcast)

Use as part of the 2/two-step method/process (Mound plus/+/&/and Broadcast)

Use mound treatment [Ortho Orthene Fire Ant Killer/alternate brand name for EPA Reg. 239-2632] as step 1/one

Use Ortho Fire Ant Killer 2681/alternate brand name as Step 2/two [of fire ant 2-step (Mound plus/+/&/and Broadcast)]

Kills the following types of ants:

Argentine

Red harvester

(4) The following MRIDs should be removed from the data matrix, as they are classified as "unacceptable" to support the product: 45298601, 46186401, 44891902

(5) Note to Reviewer: MRIDs 44137401, 44137402, and 46508101 are acceptable; however, they do not pertain to any claims on the proposed product label and should be removed from the data matrix. Note MRIDs 44137401 and 44137402 test the efficacy of granular bifenthrin against deer ticks and dog ticks. If in the future the registrant requests claims against ticks, additional data showing efficacy against lone star ticks will be required for any tick claims.

Note to PM: MRID 44891902 has been previously accepted by the Agency to support efficacy claims, but it does not meet our current criteria for efficacy studies and in addition the study is not relevant to the proposed product because there are not any proposed claims of efficacy against fleas on the label. MRID 45298601 has been previously accepted by the Agency to support efficacy claims, but it also does not meet our current criteria for efficacy studies

## TASK 2 DATA EVALUATION RECORD

### STUDY TYPE: Product Performance

MRID 495462-03. Rawlings, M.R. Speed of Fire Ant Control with a Granule Formulation Containing 0.20% Bifenthrin. November 24, 2014.

### 810.3100: Soil Treatments for Imported Fire Ants

Product Name: Ortho Fire Ant Killer 2681

EPA Reg. No. or File Symbol: 239-ETET

Decision number: 499128

DP number: 426477

Prepared for  
Registration Division (7505)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Washington, DC 20460

Prepared by  
Summittec Corporation  
Task Order No.: 2-249

Primary Reviewer:  
Patricia H. Reno, M.S.

Signature: Patricia H. Reno<sup>AE</sup>  
Date: 06/09/2015

Secondary Reviewers:  
Robert H. Ross, M.S.

Signature: Robert H. Ross<sup>AE</sup>  
Date: 06/09/2015

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross<sup>AE</sup>  
Date: 06/09/2015

Quality Assurance:  
Angela M. Edmonds, B.S.

Signature: Angela M. Edmonds  
Date: 06/09/2015

### Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

Summittec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

**STUDY TYPE:** 810.3100 Soil Treatments for Imported Fire Ants

**MRID:** MRID 495462-03. Rawlings, M.R. Speed of Fire Ant Control with a Granule Formulation Containing 0.20% Bifenthrin. November 24, 2014.

**DP BARCODE:** 426477

**DECISION NO:** 499128

**SUBMISSION NO:** 962823

**SPONSOR:** The Scotts Company LLC  
14111 Scottslawn Road  
Marysville, Ohio 43041

**TESTING FACILITY:** Auburn University  
Department of Entomology & Plant Pathology  
301 Funchess Hall  
Auburn, AL 36849

**STUDY DIRECTOR:** Michael Ceddia, Ph.D.

**SUBMITTER:** Jane Rothwell, Sr. Analyst

**STUDY COMPLETED:** 24/11/2014

**CONFIDENTIALITY CLAIMS:** None

**GOOD LABORATORY PRACTICE:** "This study does not meet the requirements of 40 CFR Part 160, and differs in the following ways:  
  
1. The study was not conducted under Good Laboratory Practice standards."

**TEST MATERIAL:** PRODUCT NAME: Ortho Fire Ant Killer 2681  
EPA REGISTRATION NUMBER OR FILE SYMBOL: 239-ETET  
ACTIVE INGREDIENT NAME: Bifenthrin  
CHEMICAL NAME: NA  
A.I. %: 0.20%  
PC CODE: Not given  
CAS NO.: Not given  
FORMULATION TYPE: Granules  
PRODUCT APPLICATION RATE(S) g/m<sup>2</sup>:

Apply ½ cup of Ortho Fire Ant Killer 2681 [product name] over each fire ant mound. A 4 ft. diameter circle around the mound should also be treated. If the soil is not moist, then it is important to irrigate before application. After applying the product, drench the mounds with 1 to 2 gallons of water. .  
ACTIVE INGREDIENT APPLICATION RATE(S)g/m<sup>2</sup>:  
0.2 lb Bifenthrin/acre

**PROPOSED LABEL  
MARKETING CLAIMS:**

Controls/kills/suppresses mounds in 15 minutes; Starts killing fast/immediately

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## STUDY REVIEW

**Purpose:** To document the speed of fire ant control in a third location with the use of 0.20% Bifenthrin granule formulation in support of previously submitted and approved data.

### **MATERIALS AND METHODS**

**Test Location:** FarmLinks Research & Demonstration Golf Course in Fayetteville, AL.

**Test Material(s):** Ortho Fire Ant Killer 2681 which is the same as the labeled product. Bifenthrin 0.20%.

**Test Species Name, Life Stage, Sex and Age:** Red Imported Fire Ant, *Solenopsis invicta*

**Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted:** Fire ant mounds were scouted along the entrance road to the FarmLinks golf course to confirm activity 24 hours prior to treatment. Randomized complete block design was utilized. The mounds were divided into three blocks of ten within each replicate and treatments were randomly assigned to blocks within the replicate. There was only one replicate containing 10 mounds for the untreated control. Each mound was located with a GPS/GIS system for relocation.

**List the treatments including untreated control (express application rate as g/m<sup>2</sup>):**

Treatments were applied to mounds in the Ortho Fire Ant Killer (standard) and to the Ortho Test Product plots on October 14, 2014. On October 15, 2014, the DG Lite 150 treatment was applied and untreated control mounds were rated. At the time of treatment, 95 grams of product (0.19 g Bifenthrin) was directly applied to the mound and an area surrounding it, up to 3 feet radius. Two gallons of water was then applied to each plot with enough force to break the top of the mound.

**Number of replicates per treatment:** 3 replicates of 10 mounds (30 mounds per treatment) and one untreated control replicate of 10 mounds.

**Number of individuals per replicate:** NA - active fire ant mounds

**Length of exposure to treatment (time in seconds, minutes or hours):** Continuous following initial treatment.

**Were tested specimens transferred to clean containers?** NA

**Experimental conditions (state relative humidity, temperature, and photoperiod):**

OBSERVATION	TARGET		ACTUAL		
	BEFORE	DAY OF	10/13	10/14	10/15
TEMPERATURE (°F)	70-95	70-95	80° F	75° F	69° F
TEMPERATURE (°F) - SOIL				71° F	68° F
RELATIVE HUMIDITY (%)			38	56	53

**Data or endpoints collected/recorded:** Mounds were evaluated for activity and mortality at 1, 2, 3, 4, 5, 10, 15, 20, and 30 minutes after application. All mounds were re-evaluated at 40 days after treatment. Product effectiveness was evaluated using an Efficacy Rubric rating scale as follows:

- 0 - Complete ant /mound control; no activity or movement observed; all visible ants in the treated area dead.
- 1 - Acceptable control; ant activity and movement observed; < 10% of ants in treated area alive but all exhibiting signs of morbidity and/or are moribund; 90%+ of ants are dead.
- 2 - Significant reduction in ant activity and movement observed; < 30% of ants in treated area alive but all exhibiting signs of morbidity and/or are moribund; 70-90% of ants are dead.
- 3 - Moderate reduction in ant activity and movement; ~50% of ants in treated area exhibiting signs of mortality or morbidity; 50-70% of ants are dead.
- 4 - Minimal reduction in ant activity and movement; < 30% of all ants in treated area exhibit signs of mortality or morbidity.
- 5 - No visible reduction in ant activity and movement; < 10% of all ants in treated area exhibit signs of mortality or morbidity.

Assessments were terminated after two successive 0 ratings. Final data on mound activity was taken on November 24, 2014.

**Data analysis:** Mean visual rating of fire ant mounds; Tukey's Studentized Range Test,  $P > 0.05$

## RESULTS

Mean visual rating of fire ant mound treatments within the first 30 minutes are presented in Table 1 and Table 2 presents the results 40 days post application.

Table 1: Mean visual rating of fire ant mound treatments. Values are defined by the rubric stated above, < 1 ~ 90% control. Values followed by a different letter are statistically significant (Tukey's Studentized Range Test,  $P>0.05$ ).

Treatment	Evaluation Time in Minutes								
	1	2	3	4	5	10	15	20	30
Water	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a
Blank DG Lite 150 Carrier	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a	5.00 a
Ortho MAX Fire Ant Killer Broadcast Granules (0.2% bifenthrin)	4.20 b	4.00 b	3.57 b	3.10 b	2.63 b	1.63 b	0.73 b	0.43 b	0.10 b

Table 2: Number of mounds alive 40 days post application.

Treatment	Replication		
	1	2	3
Water	9, 1 moved, found	NA	NA
Blank DG Lite 150 Carrier	8, 2 moved or dead, not found	9, 1 moved, found	9, 1 moved, found
Ortho MAX Fire Ant Killer Broadcast Granules (0.2% bifenthrin)	0	0	0

The Ortho Fire Ant Killer (standard) and the Ortho Test product both worked very fast. At the 1 minute rating period, both had significantly less activity than the control mound or the DG Lite 150 ( $P=0.003$ ). Mound control was > than 90% by 15 minutes. No live mounds in the treated plots were found on November 24.



### **Study Author's Conclusions**

The study authors concluded that Ortho Max Fire Ant Killer Broadcast Granules (0.2% bifenthrin) achieved excellent control of fire ant mounds in a short period of time. Acceptable control was achieved within 15 minutes and was maintained for 40 days post application. In addition, the authors stated that given these results from Alabama and previously submitted and approved data from Texas and Georgia (MRID 48387492), they made the following claims for a formula containing 0.2% bifenthrin: kills fire ants fast; kills fire ants in minutes; and kills fire ants in 15 minutes.

### **Reviewer's Conclusions**

This was a well-conducted study. Both the control and blank DG Lite 150 carrier received efficacy rubric ratings of 5 at all evaluation times, indicating no visible reduction in ant activity and movement and <10% of all ants exhibited signs of mortality or morbidity. Control of fire ant mounds was achieved within 15 minutes following application with >90% mortality. Efficacy was statistically significant from the untreated control, and carrier only treatment within 1 minute.

### **Reviewer's Recommendations**

Acceptable. This study supports the following claims for speed of action for mound treatments against fire ants: starts killing fire ants in minutes, kills fire ants in 15 minutes.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

REGISTRATION DIVISION (7505P)  
OFFICE OF PESTICIDE PROGRAMS

FEE

This Document Contains Confidential Information

DP BARCODE No.: 426476: File Symbol No. 239-ETET: PRODUCT NAME: Ortho Fire  
Ant Killer 2681: PC Code(s):128825: Decision No. 499128: Action Code: R 310: Food Use:  
NO [X]

DATE OUT: 05/05/15

SUBJECT: Product Chemistry Review of New End Use Product  
Product Name: Ortho Fire Ant Killer 2681

FROM: Indira Gairola, Product Chemistry Team (4)  
CITAB / Registration Division (7505P)

05/05/15  
SRM 5-5-15

TO: Maggie Rudick / Kable Davis PM 03  
Insecticide Branch / Registration Division (7505P)

Company Name: The Scotts Company.  
Formulation Type Insecticide (Granular Solid)

INTRODUCTION:

The registrant submitted an application for registration of the new end use product "Ortho Fire Ant Killer 2681". Registrant has submitted Basic CSF, alternate CSF A & B all dated 06/05/14. Applicant is submitting (MRID #s) 495462-01 & 437805-01 for product chemistry data to support this registration application. Applicant claims the subject product to be similar to EPA Reg. # 279-3207.

CITAB has been asked to determine the acceptability of the aforementioned product chemistry data and CSFs.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient (s) Bifenthrin (0.2%).

2. Has the registrant claimed substantial similarity to a registered product?

☒ Yes if yes give the registration number of the cited product

EPA Reg. # 279-3207

3. All of the source materials of the active ingredient are derived from registered sources-

☒ Yes ☐ No ☐ Pending Registration

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled food uses. ☒ Yes

5. Confidential Statement of Formula(s):

☒ Proposed Basic dated: 06/05/14 Resubmitted date

☒ Proposed Alternate A&B dated: 06/05/14

Proposed Alternate comply with 40CFR§152.43: ☒ Yes; ☐ No ☐ NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2)

☒ Yes; ☐ No; if not, explain below:

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs. other Ingredient t?)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☒ NA

Isomeric ratios ☒ NA

Soluble Arsenic ☒ NA

Acid Equivalent ☒ NA

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite: ☐ Yes ☒ No ☐ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for flammability, explosive potential or electric insulator breakdown?

☐ Yes ☐ No ☒ Please add the following statement under the heading:

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes, ☐ No; ☒ NA; if not, explain below:

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes Explain below:

Group A: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		CITAB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	Basic CSF 06/05/14
830.1600	Description of materials used to produce the product		X		A	495462-01
830.1650	Description of formulation process		X		A	495462-01
830.1670	Discussion on the formation of impurities		X		A	495462-01
830.1700	Preliminary analysis			NA		Basic CSF 06/05/14
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	495462-01

A = Acceptance, N = Not Acceptable, G = Data Gap,

W = Waiver Request, I = In Progress, NA = Not Applicable, U = Upgradeable.

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	CITAB's Assessment of Data	MRID Nos. Cited
830.6303	Physical State	Granular Solid	A	437805-01
830.6315	Flammability	Does not contain combustible ingredients	NA	437805-01
830.6314	Oxi/ Red	Does not contain Oxidizing / Reducing agents	NA	437805-01
830.6316	Explodability	Does not contain explosive chemicals	NA	437805-01
830.6320	Corrosion Characteristic	Based on the corrosion results of the uncoated bag, no corrosion of the polyethylene coated bag is anticipated under the conditions of the corrosion, test.	A	437805-01
830.6317	Storage Stability	Determination of this property was not addressed in this study	G	437805-01
830.7000	pH	6.27 at 25°C	A	437805-01
830.7100	Viscosity	Solid	NA	437805-01
830.7300	Density (units)	4.69 g/cc at 25 °C	A	437805-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,  
 NA = Not applicable, I = In progress, U = Upgradeable.

## CONCLUSIONS:

CITAB has reviewed submitted Basic CSF, alternate CSF A & B all dated 06/ 05/14 and product chemistry data corresponding to guideline 830 series, group A & group B for the proposed subject product "Ortho Fire Ant Killer 2681" and concluded:

1. The data corresponding to 830 series group A for the proposed subject "Ortho Fire Ant Killer" 2681 are acceptable.
2. Product chemistry Data for 830 series group B are acceptable.
3. Applicant needs to submit Storage stability (guideline 830.6317) studies when complete for the proposed subject product (See summary of findings Table #2). It is stated in MRID # 437805-01 storage stability (63-17) will be addressed in a separate study.
- 4 Basic CSF, alternate CSF A & B all dated 06/ 05/14 are acceptable.
5. The subject is considered to be similar to EPA Reg. # 279-3207 from product chemistry point of view.
6. The proposed label was screened as it pertains to the product chemistry requirements.
7. The final review of the proposed label and uses are the purview of the PM team.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**CONTAINS CBI – DO NOT RELEASE TO REGISTRANT**

SIMILARITY CLINIC MEMORANDUM:

Subject: EPA Reg. No.: 239-ETET/Ortho Fire Ant Killer 2681  
DP Barcode: 426332  
PC Code: 128825

From: Marianne Lewis, Biologist  
Insecticides/Rodenticides Branch  
Registration Division (7505P)

*Marianne Lewis*  
*JCR 3/24/15*

To: Kable Davis, PM 3  
Invertebrate Vertebrate Branch 1  
Registration Division (7505P)

Applicant: The Scotts Company, LLC  
d/b/a The Ortho Group  
P.O. Box 190  
Marysville, OH 43040

FORMULATION FROM EPA Reg. No. 239-ETET LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Bifenthrin: .....	0.2%
<u>Inert Ingredient(s):</u> .....	99.8%
Total	100.0%

\*Inert ingredient information may be entitled to confidential treatment\*

\*Product ingredient source information may be entitled to confidential treatment\*

BACKGROUND: The registrant is claiming substantial-similarity to EPA Reg. Nos. 279-3207 & 239-2681 and is citing specific MRID's to support the registration of their new product, EPA Reg. No. 239-ETET. The MRID's are as follows: 437805-02 (81-1), 437805-03 (81-2), 437805-04 (81-4), 437805-05 (81-5), 437805-06 (81-6). A waiver request was submitted for the acute inhalation study requirement. The test material used in the cited studies was EPA Reg. No. 279-3163. The percentage active ingredient is the same in both the test material and the subject product. The inerts vary slightly. The subject product contains a carrier and its MSDS states that [REDACTED] MSDS states under "Special Precautions: [REDACTED] The acute inhalation study will be waived and classified as Toxicity Category III. If the registrant disagrees with this an attrition study should be conducted to demonstrate that respirable fines are not created. The protocol number for the attrition study is ASTM E728-91.

Initially when they came in, EPA Reg No. [REDACTED]

[REDACTED] Those studies/products will not support the subject product.

After reviewing the CSF's from the subject product and the test material used in the studies cited in the Data Matrix it has been determined that they are similar. Therefore, the following acute toxicity categories will be assigned to the subject product: acute oral (81-1) – III; acute dermal (81-2) – III; acute inhalation (81-3) – III; primary eye irritation (81-4) – III; primary skin irritation (81-5) – IV; and will be classified as a non sensitizer (81-6).

#### RECOMMENDATIONS:

- The subject product will be assigned the Toxicity Categories listed above to support the registration of EPA Reg. No. 239-ETET.
- The subject product will be classified as a non sensitizer.

The acute toxicity profile for EPA Reg. No. 239-ETET is currently:

Acute Oral	III
Acute Dermal	III
Acute Inhalation	III
Primary Eye	III
Primary Dermal	IV
Skin sensitization	non sensitizer

NOTE: The acute toxicity requirements have been satisfied for the subject product.



**LABELING:**

**ID #:** 000239-ETET            ORTHO FIRE ANT KILLER 2681

**SIGNAL WORD:**            CAUTION

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS:**

Harmful if swallowed. Harmful if absorbed through skin. Harmful if inhaled. Causes moderate eye irritation. Avoid contact with eyes, skin, or clothing. Avoid breathing dust. Wear long sleeved shirt and long pants, shoes, socks and chemical resistant gloves (such as or made out of any waterproof material, selection category A).

**FIRST AID:**

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

**IF INHALED:** Move person to fresh air. If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor for further treatment advice.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

**USER SAFETY RECOMMENDATIONS:**

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

21-Day Screen Completed by  
Contractor

21-Day Expires on 2-4-15

Jacket # 239-ETET

MRID# 495462

Content Screen: Recommend to ☒ Pass/Fail

11-3 Review: ☒ Pass/Fail/NA

Overall Status: Recommend to ☒ Pass/Fail

Transfer This Jacket to:

SHAUNTA HILL

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 1-14-15

Experts In-Processing Signature: B.B.

Date 1-15-15

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>239-ETET</u>		EPA Receipt Date: <u>1-14-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<u>Non-food</u>	X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)			X		
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

Documentation: Pass

- Data Matrix missing some guidelines
- Not Required per registrant (see e-mail)
- Required forms are complete.

Inerts: Pass

- Approved for non-food use.

11-3: Pass

MRIID - 495462

Status: Pass

TU 1/28/15

**Jackson, Tracy**

**From:** Rothwell, Jane <jane.rothwell@scotts.com>  
**Sent:** Monday, January 26, 2015 2:26 PM  
**To:** Jackson, Tracy  
**Subject:** Re: Application 239-ETET  
**Attachments:** [REDACTED] MSDS.pdf

Ms Jackson

Thank you for taking my call today. As discussed, the three guidelines referenced, 830.6314, 830.6321 and 830.7100 are not required for this formulation type (granule).

As for the inert ingredient in question, the msds is attached. The [REDACTED] is a synonym for [REDACTED] (the name that comes up in the search on the inert finder).

Please let me know if this satisfies your request.

Regards,

Jane Rothwell  
937-578-5984

On Mon, Jan 26, 2015 at 12:36 PM, Jackson, Tracy <jackson.tracy@epa.gov> wrote:

Dear Ms. Rothwell,

I am contacting you regarding your submission in support of **Ortho Fire Ant Killer 2681 (239-ETET)**. The following deficiencies were found:

1. The guidelines below were not listed on the data matrix. Are they required?

830.6314 – Oxidation/Reduction

830.6321 – Dielectric Breakdown Voltage

2. There is one inert that is not approved. Please see attachment.

Corrections can be sent to [jackson.tracy@epa.gov](mailto:jackson.tracy@epa.gov)

Thank You

Tracy Jackson

EPA Contractor

703-308-7227  
2777 S. Crystal Drive  
Arlington, VA 22202

Jane Rothwell  
Analyst, Regulatory Affairs  
The Scotts Company LLC d/b/a The Ortho Group  
p: 937-578-5984

## Jackson, Tracy

**From:** Jackson, Tracy  
**Sent:** Monday, January 26, 2015 12:36 PM  
**To:** 'Jane.Rothwell@Scotts.com'  
**Subject:** Application 239-ETET  
**Attachments:** Inert Status 2.doc

Dear Ms. Rothwell,

I am contacting you regarding your submission in support of **Ortho Fire Ant Killer 2681 (239-ETET)**. The following deficiencies were found:

1. The guidelines below were not listed on the data matrix. Are they required?

830.6314 - Oxidation/Reduction

830.6321 - Dielectric Breakdown Voltage

830.7100 - Viscosity

2. There is one inert that is not approved. Please see attachment.

Corrections can be sent to [jackson.tracy@epa.gov](mailto:jackson.tracy@epa.gov)

Thank You

Tracy Jackson  
EPA Contractor  
703-308-7227  
2777 S. Crystal Drive  
Arlington, VA 22202



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 15, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-499128  
EPA File Symbol or Registration Number: 239-ETET  
Product Name: ORTHO FIRE ANT KILLER 2681  
EPA Receipt Date: 14-Jan-2015  
EPA Company Number: 239  
Company Name: THE SCOTTS COMPANY

JANE ROTHWELL  
THE SCOTTS COMPANY  
D/B/A THE ORTHO GROUP  
PO BOX 190  
MARYSVILLE, OH 43041-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE(S) OF ACTIVE INGREDIENT(S); INCLUDES PRODUCTS CONTAINING TWO OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER REGISTERED PRODUCTS; REQUIRES REVIEW OF DATA PACKAGE WITHIN RD ONLY; INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY; PRODUCT CHEMISTRY; ACUTE TOXICITY; PUBLIC HEALTH PEST EFFICACY; CHILD RESISTANT PACKAGING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

A handwritten signature in cursive script that reads "Teresa Downs".

Front End Processing Staff

Information Technology & Resources Management Division



**Fee for Service**

{962823+~

This package includes the following

☒ New Registration

☐ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

3

Receipt No.

S-

962823

EPA File Symbol/Reg. No.

239-ETET

Pin-Punch Date:

1/14/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R 310

Granted:

R 310

Amount Due: \$ 5,048

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Aswathy Balan

Date: 1/15/15

Remarks:

*Similarity Clinic*

Receipt for Section 3			
S:	962823	Milestone Email:	
Regulatory Type:	Product Registration - Section 3	Resubmission:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Application Type:	New Registration	Fee For Service:	<input checked="" type="radio"/> Yes <input type="radio"/> No
Company:	239 THE SCOTTS COMPANY	Billable:	<input checked="" type="radio"/> Yes <input type="radio"/> No
<div>Print Letter Enter More Information Tracking</div>			
Risk Manager:	Registration Division, Risk Management Team 3		
Product #:	239-ETET	Product Name:	THE ORTHO GROUP WORTH O FIRE ANT KILLER
Override#:			
Me Too Section3:		Me Too Product Name:	
Application Date:	06-Jan-2015	OPP Rec'd Date:	14-Jan-2015
Front End Date:	14-Jan-2015	Risk Manager Send Date:	
FFS Due Date:		Negotiated Due Date:	
OPP Target Date:			
Fast Track:	<input checked="" type="checkbox"/>	New Ingredient:	<input type="checkbox"/>
Receipt Description:		View/Edit	
Submission of New Registration		New Ingredient Request Date:	
		New Ingredient Received Date:	
Form A:	<input checked="" type="checkbox"/>	Signature Date:	
Form B:	<input type="checkbox"/>	Signature Date:	

**Receipt****Your payment is complete**

Pay.gov Tracking ID: 25J0A10V

Agency Tracking ID: 74726051722

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

**Payment Information**

Payment Type: Debit or credit card

Payment Amount: \$5048.00

Transaction Date: 12/22/2014 11:33:56 AM EST

Payment Date: 12/22/2014

Registration Number: 239-NEW

Company Name: The Ortho Group

Company Number: 239

Action Code: R310

**Account Information**

Card Holder Name: Connie Christian

Billing Address: 14111 Scottslawn Rd.

Billing Address 2:

City: Marysville

Country: United States

State/Province: OH

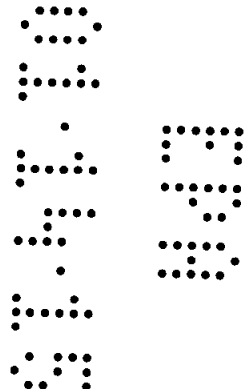
ZIP/Postal Code: 43041

Card Type: Visa

Card Number: \*\*\*\*\*3991

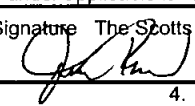
**Email Confirmation Receipt**

No confirmation email was provided during the creation of this transaction.



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 05-31-98

<b>EPA</b> United States <b>Environmental Protection Agency</b> Washington, DC 20460		<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	OPP Identifier Number
<b>Application for Pesticide - Section I</b>			
1. Company/Product Number 239-NEW		2. EPA Product Manager Kable Davis	
4. Company/Product (Name) The Ortho Group / Ortho Fire Ant Killer 2681		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code)  The Scotts Company d/b/a The Ortho Group PO Box 190 Marysville, OH 43040  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3)(b)(I), my product is similar or identical in composition and labeling to:  EPA Reg. No.    279-3207 and 239-2681  Product Name    Talstar Fire Ant-x Fire ant Killer, Ortho Fire Ant Killer	
<b>Section II</b>			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated: <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below.	
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Submission of new registration -- PRIA R310. See cover letter for details. Email: Jane.Rothwell@Scotts.com			
<b>Section III</b>			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No  <b>*Certification must be submitted</b>	Unit Packaging <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If "Yes"    No. per Unit Packaging wgt.    Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"    No. per Package wgt.    Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) bag/ bottle
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 1 lb to 12 lb	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
<b>Section IV</b>			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jane Rothwell		Title Analyst, Regulatory Affairs	
		Telephone No. (Include Area Code) (937) 576-3984	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature The Scotts Company BY: 		3. Title Analyst, Regulatory Affairs	
4. Typed Name Jane Rothwell		5. Date January 6, 2015	



***The Scotts Company LLC***

*and Subsidiaries*

January 6, 2015

Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

**ATTENTION:** Kable Davis (PM 3)  
Invertebrate-Vertebrate Branch 1

**SUBJECT:** The Scotts Company d/b/a The Ortho Group  
Ortho Fire Ant Killer 2681  
EPA Reg. No. 239-NEW  
PRIA Category R-310

Dear Mr. Davis:

The Scotts Company d/b/a The Ortho Group (hereafter Scotts) is applying for a new registration, Ortho Fire Ant Killer 2681. This is an end-use product, containing 0.2% bifenthrin for use on fire ants. We believe this action should be processed as a PRIA Category R-310 decision, including a fee of \$5048.00 and a 7-month decision time.

We are using the selective cite-all option to support toxicity (except inhalation-see Note below), product chemistry, and efficacy data for this product. The basic formula is substantially similar to FMCs (Co. No. 279) EPA Reg. No. 279-3207, Talstar Fire Ant-X Fire Ant Killer. A letter of authorization (LOA) from FMC is enclosed with this submission. Scotts label is similar and relies on the same data that supported EPA Registration 239-2681- Ortho Fire Ant Killer. Specific mrids for Scotts own data are outlined on the data matrix. Scotts is submitting our own Group A Product Chemistry to outline the manufacturing process.

Note: FMC requested a waiver on their data matrix to satisfy the requirement for inhalation-OPPTS 870.1300. Scotts is also requesting a waiver; the explanation is outlined in the report enclosed "Acute Inhalation Toxicity Waiver." The waiver is being submitted in study format per PR Notice 2001-2. Scotts product meets the definition of a granular pesticide and satisfies the requirements outlined.

To support efficacy claims on the label for speed, the data matrix enclosed cites mrid 48387402- "Speed of fire ant control with a granule formulation containing 0.05% zeta-cypermethrin and 0.20 % bifenthrin." This study, conducted by Scotts, was done in support of a registration for two active ingredients, bifenthrin and zeta-cypermethrin. The control was bifenthrin only (at the same % a.i. - 0.2%). Of the three locations tested (Apopka, FL, Marlin, TX, and Sparks, GA) - one location (FL) did not achieve the 15 minute claim. The other two locations were successful at 10 minutes. We believe the Florida study was an anomaly, and therefore Scotts conducted an additional study to re-test for the 15 minute claim.

Results from this study were favorable for a 15 minute claim. We respectfully ask that you review the results of both the previously submitted study (mrid 48387402) and the study being submitted with this application for the review of the speed claims on this label.

14111 Scottslawn Road Marysville, Ohio 43041 937-644-0011


We have also included on our data matrix a citation for "DG-Lite a rapid release granule technology."  
Some speed and product performance claims were added to this label as a result of the data generated from this study.

A Basic CSF, Alternate (ALT) A, and Alt B are also enclosed.

The enclosed Transmittal document outlines the documents to support this submission.

Please contact me at 937-578-5984 or by email at [Jane.Rothwell@Scotts.com](mailto:Jane.Rothwell@Scotts.com) should you have any questions regarding this submission.

Sincerely,



Jane Rothwell  
Analyst, Regulatory Affairs  
Enclosures

# TRANSMITTAL DOCUMENT

## 1. NAME AND ADDRESS OF SUBMITTER:

The Scotts Company d/b/a The Ortho Group  
PO Box 190  
Marysville, Ohio 43040

## 2. REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED:

New product registration  
Ortho Fire Ant Killer 2681  
EPA File Symbol- 239-NEW

## 3. TRANSMITTAL DATE:


January 6, 2015

## 4. LIST OF SUBMITTED STUDIES:

Volume	Study Title	Guideline Number	MRID
I	<u>Administrative Materials</u>  Cover Letter  Transmittal Document  Receipt of Payment of PRIA fee; PRIA: R310, \$5048.00  EPA Form 8570-1, Application for Pesticide Registration  EPA Form 8570-34, Certification with Respect to Data Citation  EPA Form 8570-35, Data Matrix (EPA private and public versions)  EPA Form 8570-27, Formulator's Exemption Statement  EPA Form 8570-4, Confidential Statement of Formula(CSF) Basic- (dated 06/05/2014), and ALT A (dated 06/05/2014), ALT B (dated 06/05/2014) (two copies of each)  Product label (five copies)  LOA- FMC Corporation (Company No. 279)	N/A	
II	Product Identity, Composition, and Analysis for product- Ortho Fire Ant Killer 2681- EPA Reg. 239-NEW; Author: Jason Hoy, The Scotts Company LLC, Study SS-340A, ten (10) pages, (plus four (4) pages Confidential Attachment)	830.1550  830.1600  830.1650  830.1670  830.1750  830.1800	

III	Ortho Fire ant Killer 2681, EPA Reg. 239-NEW, S-9891 (30*1345), Acute Inhalation Toxicity Waiver, OPPTS 870.1300, Author: Jack Schmansky, November 18, 2014, The Scotts Company LLC, SS-343, Four (4) pages	870.1300	
IV	Speed of Fire Ant Control with a Granule Formulation Containing 0.20% Bifenthrin, OPPTS 810.3100, Author: Matthew R. Rawlings, M.S., November 24, 2014, The Scotts Company LLC, Trial # C-14-C-1-274-01-MRR, Forty Seven (47) pages	810.3100	

**Company Official:** Jane Rothwell, Analyst, Regulatory Affairs

**Signature:** 

**Company Name:** The Scotts Company d/b/a The Ortho Group

**Company Contact:** Jane Rothwell

**Phone Number:** 937-578-5984





VIA FEDERAL EXPRESS

FMC Corporation  
1735 Market Street  
Philadelphia, PA 19103  
USA

December 15, 2014

215.299.6000  
fmc.com

Mr. Kable Davis (PM-3)  
U.S. Environmental Protection Agency  
Document Processing Desk  
Office of Pesticide Programs (7504P)  
Room S4900, One Potomac Yard  
2777 Crystal Drive  
Arlington, VA 22202

Dear Mr. Davis:

Subject: **Ortho Fire Ant Killer 2681 (EPA Reg. No. 239-NEW)**

FMC Corporation understands that The Scotts Company d/b/a The Ortho Group is applying for registration of the subject product containing the active ingredient bifenthrin, which is similar to FMC's registration of Talstar Fire Ant-X Fire Ant Killer (EPA Reg. No. 279-3207). The access granted herein applies only to the singular registration application as specified, and may not be utilized for any other registration efforts unless subsequently authorized by FMC Corporation. We authorize EPA to consider and use the below listed data submitted by FMC Corporation in support of The Ortho Group's registration application as of the date of this letter:


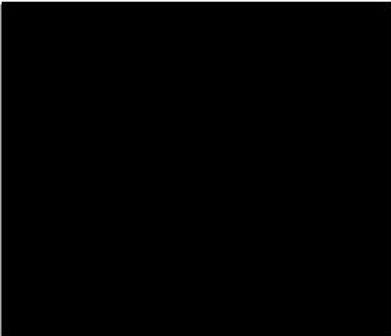


<b>MRID #</b>	43780502	440219-01
	43780503	441374-01
	43780504	441374-02
	43780505	448919-02
	43780506	452986-01
	43780501	46186401
	41539001	46508101

This authorization does not imply any waiver or abdication of our rights in these data or any right to use these data by anyone for use other than specified herein. The Ortho Group is not authorized to receive copies or other access to the above referenced data, or to rely on that data to support The Ortho Group pesticide registrations which may use an active ingredient not supplied by FMC. FMC retains the right to unilaterally revoke the authorization in this letter if The Ortho Group ceases to purchase FMC's technical material or manufacturing use products, or otherwise violates any condition of this letter.

Sincerely,

Evan Parenti  
Product Registration Manager  
215-299-5875  
[evan.parenti@fmc.com](mailto:evan.parenti@fmc.com)

Form approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

 <div style="text-align: center;"> United States  Environmental Protection Agency  Washington, DC 20460  <b>Formulator's Exemption Statement</b>  (40 CFR 152.85) </div>		
Applicant's Name and Address  The Scotts Company d/b/a The Ortho Group PO Box 190 Marysville, OH 43040	EPA File Symbol/Registration Number 239-NEW	
	Product Name Ortho Fire Ant Killer 2681	
	Date of Confidential Statement of Formula (EPA Form 8570-4) 06/05/2014	
As an authorized representative of the applicant for registration of the product identified above, I certify that:  (1) This product contains the following active ingredient(s): Bromethalin   (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).  (3) Indicate by checking (A) or (B) below which paragraph applies:  <input checked="" type="checkbox"/> (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1). <div style="text-align: center;">OR</div> <input type="checkbox"/> (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.  (4) The following active ingredients in this product qualify for the formulator's exemption.		
<b>Source</b>		
<b>Active Ingredient</b>  bifenthrin	<b>Product Name</b> 	<b>Registration Number</b> 
Signature: 	Name and Title: Jane Rothwell, Analyst Regulatory Affairs	Date: date 1-6-15


**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**
**401 M Street, S.W.  
WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address and Telephone Number  
The Scotts Company LLC, d/b/a The Ortho Group  
P.O. Box 190, Marysville, OH 43040 (937)-578-5984

EPA Registration Number/ File Symbol  
239-NEW

Active Ingredient(s) and/or representative test compound(s):  
bifenthrin (CAS # 82657-04-3)

Date  
January 6, 2015

General use pattern(s) (list all those claimed for this product using 40 CFR Part 158)  
Outdoor residential

Product Name  
Ortho Fire Ant Killer 2681

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

1-6-15

Typed or Printed Name and Title

Jane Rothwell, Analyst, Federal Registrations

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGA).  
 Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or (NO) (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	✓					
830.1600	Description of materials used to produce the product	✓					
830.1650	Description of formulation process	✓					
830.1670	Discussion on the formation of impurities	✓					
830.1700	Preliminary analysis <i>Not Required</i>		✓				
830.1750	Certified limits (158.345)	✓					
830.1800	Enforcement analytical method	✓					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGA	
		Yes	No	Yes	No	Yes	No
830.6302	Color	✓					
830.6303	Physical State	✓					
830.6304	Odor <i>Not Required</i>		✓				
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility) <i>Not Required</i>		✓				
830.6315	Flammability <i>Not Required</i>		✓				
830.6316	Explosibility <i>Not Required</i>		✓				
830.6317	Storage stability	✓					
830.6319	Miscibility <i>Not Required</i>		✓				
830.6320	Corrosion Characteristics	✓					
830.6321	Dielectric Breakdown Voltage <i>Not Required</i>		✓				
830.7000	pH	✓					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity <i>Not Required</i>		✓				
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	✓					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

# R 310

New products must either: 1) supply the product-specific acute toxicity 6-pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label, instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	✓			
870.1200	Acute Dermal (LD50)	✓			
870.1300	Acute Inhalation (LC50)	✓			
870.2400	Acute Eye Irritation	✓			
870.2500	Acute Dermal Irritation	✓			
870.2600	Dermal Sensitization	✓			

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants	✓				
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

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DATA MATRIX

Date	January 6, 2015	EPA Reg. No./File Symbol	239-NEW	Page 1 of 2	
Applicant's/Registrant's Name & Address: The Scotts Company d/b/a Ortho Group P.O. Box 190 Marysville, OH 43040		Product Ortho Fire Ant Killer 2681			
Ingredient(s): bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

830.1550	Product Identity and Composition	Submitted	Scotts Co. # 239	OWN	
830.1600	Description of the Materials Used to Produce the Product	Submitted	Scotts Co. #239	OWN	
830.1620	Description of production process	n/a	-	Not required	
830.1650	Description of the formulation process	Submitted	Scotts Co. # 239	OWN	
830.1670	Discussion of Formation of Impurities	Submitted	Scotts Co. # 239	OWN	
830.1700	Preliminary Analysis	n/a	-	Not required	
830.1750	Certified Limits	Submitted	Scotts Co. # 239	OWN	
830.1800	Enforcement Analytical Method	Submitted	Scotts Co. # 239	OWN	
830.6302	Color	43780501	FMC Corp. Co. # 279	PER	
830.6303	Physical State	43780501	FMC Corp. Co. # 279	PER	
830.6304	Odor	n/a	-	Not required	
830.6315	Flammability	n/a	-	Not required	
830.6316	Explosibility	n/a	-	Not required	
830.6317	Storage Stability	41539001	FMC Corp. Co. # 279	PER	
830.6319	Miscibility	n/a	-	Not required	
830.6320	Corrosion Characteristics	43780501	FMC Corp. Co. # 279	PER	
830.7000	pH	41539001	FMC Corp. Co. # 279	PER	
830.7300	Density	43780501	FMC Corp. Co. # 279	PER	
870.1100	Acute Oral Toxicity	43780502	FMC Corp. Co. # 279	PER	
870.1200	Acute Dermal Toxicity	43780503	FMC Corp. Co. # 279	PER	
870.1300	Acute Inhalation Toxicity	Waiver - Submitted	Scotts Co. # 239	OWN	
870.2100	Acute Eye Irritation	43780504	FMC Corp. Co. # 279	PER	
870.2500	Acute Dermal Irritation	43780505	FMC Corp. Co. # 279	PER	

Signature

Name and Title: Jane Rothwell, Analyst, Regulatory Affairs

Date  
1-6-15



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Ingredient(s): bifenthrin					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Dermal Sensitization	43780506	FMC Corp. Co. # 279	PER	
Series 810	Product Performance				
810.3100	Six month residual -Fire ant	440219-01	FMC Corp. Co. # 279	PER	
810.3300	Bifenthrin control of deer ticks in Turfgrass	441374-01	FMC Corp. Co. # 279	PER	
810.3300	Bifenthrin control of dog ticks in Turfgrass	441374-02	FMC Corp. Co. # 279	PER	
810.3300	Efficacy of Broadcast Applications of Bifenthrin liquid and granular formulations to turfgrass for cat flea control	448919-02	FMC Corp. Co. # 279	PER	
810.3300, 810.3500	Efficacy of Broadcast Applications of Bifenthrin	452986-01	FMC Corp. Co. # 279	PER	
810.3500	Efficacy of Granular Formulations of Bifenthrin on Scorpions and Chiggers	46186401	FMC Corp. Co. # 279	PER	
810.3500	Efficacy of Granular Formulations of Bifenthrin on Scorpions	46508101	FMC Corp. Co. # 279	PER	
810.3100	Residual Claim- Fire Ants	46180801	Scotts Co. #239	OWN	
810.3100	Residual Claim- Fire Ants	46809101	Scotts Co. #239	OWN	
810.3100	Suppression -Fire Ants	46809102	Scotts Co. #239	OWN	
810.3100	Speed of fire ant control (granule)	48387402	Scotts Co. #239	OWN	
810.1000	Dg lite a rapid release granule	48387401	Scotts Co. #239	OWN	
810.3100	Speed of fire ant control	submitted	Scotts Co. #239	OWN	

914100

Signature

Name and Title: Jane Rothwell, Analyst, Regulatory Affairs

Date  
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